Proposed Changes to Medical Test Site Rules April 2004

by Gail Neuenschwander

Revisions to the federal CLIA regulations were published in the January 24, 2003 Federal Register. The changes were effective April 24, 2003. The state Medical Test Site (MTS) Rules, Chapter 246-338 WAC, will now be changed so they are consistent with the CLIA regulations. The MTS rules must be at least as stringent as CLIA in order for Washington laboratories to maintain an exemption from federal CLIA regulation.

Following is a summary of the proposed changes to the MTS rules. The changes will be made through the official state rulemaking process. Notification will be sent to all Medical Test Sites when the appropriate documents are filed and the hearing date is set.

If you need a copy of the current MTS rules, you can download from the web at: www.leg.wa.gov/wac. Select Title 246 - Health, Department of; select 246-338 Medical Test Site rules.

Send any comments that you have on the proposed changes by **April 30, 2004** to:

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WAC 246-338-010 Definitions

- Calibration verification - changed wording in the definition from assaying of calibration materials to assaying of materials of known concentration;
- HCFA changed to CMS - Centers for Medicare & Medicaid Services;
- Subspecialty - updated subspecialty categories to eliminate other chemistry, other hematology and other immunohematology; changed blood group to ABO Grouping and crossmatching to compatibility testing;

WAC 246-338-060(1)(c) Personnel

- Eliminated the language regarding the grandfather clause for persons who passed an exam for director conducted by United States Public Health Service prior to July 1, 1970, as this is part of the CLIA personnel standards which are cross-referenced (42 CFR Part 493 Subpart M);

WAC 246-338-070 Records

Requisitions (1)

- Added language: (b) Name and address or other suitable identifiers of the authorized person ordering the test;
- Revised language: (f) Sex and age of patient or date of birth of the patient ~~if appropriate~~;

Test Reports (3)

- Added additional language that must be included on the test report: (c) Patient name and identification number, or a unique patient identifier and identification number; specimen source, when appropriate;

Cytology Reports (4)

- Updated reference to the 2001 Bethesda system of terminology;

Cytogenetic Reports (6)

Updated language:

- (b) Include the number of cells counted and ~~karyotyped~~ analyzed;
- (c) Include a summary and interpretation of the ~~karyotypes findings~~ observations; and
- (d) Use the International System for Cytogenetic Nomenclature;

Record/Slide/Tissue Retention Schedule

Added language:

- (8) The medical test site must retain records, slides and tissues as described in Table 070-1, under storage conditions that ensure proper preservation;
- (9) If the medical test site does not have sufficient space to store all records on-site, the records must be retrievable within a reasonable period of time, not to exceed 48 hours;

Table 070-1

- Clarified that test records include instrument printouts, if applicable;

WAC 246-338-080 QUALITY ASSURANCE

Added language:

- (2) The quality assurance plan must include mechanisms or systems to:
  (h) Ensure that specimens are properly labeled, including patient name or unique patient identifier and, when appropriate, specimen source;
  (i) Ensure confidentiality of patient information through all phases of the testing process;
- (4) When results of control or calibration materials fail to meet the established criteria for acceptability, the medical test site must have a system in place to determine if patient test results have been adversely affected. The system must include:
  (a) A review of all patient test results obtained in the unacceptable test run; and
  (b) A review of all patient test results since the last acceptable test run.
- (6) The owner must:
  (b) Ensure that molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and production detection, and as applicable, reagent preparation;
  (c) Establish, ~~post~~ make accessible, and observe safety precautions to ensure protection from physical, chemical, biochemical, and electrical hazards and biohazards;

WAC 246-338-090 QUALITY CONTROL

Added language:

- (6) (g) Rotate control material testing among all persons who perform the test;
- (7) Validation for moderate complexity testing: If using the reference range provided by the manufacturer, verify that it is appropriate for the patient population;

Table 090-1 General Quality Control Requirements

- Added immunohistochemical stains to types of stains that must have positive and negative controls run with each time of use;

- **Eliminated Table 090-2 Calibration and Calibration Checks - Moderate Complexity Testing**;

- **Renamed Table 090-3 Calibration and Calibration Checks - High Complexity Testing** to Table 090-2 Calibration and Calibration Verification - Moderate and High Complexity Testing, as the requirements for calibration and calibration verification now apply to both moderate and high complexity testing;

Table 090-5 Quality Control Procedures - Hematology

- Automated: Changed the requirement for 2 levels of reference materials every 8 hours to 2 levels each day of testing;

Table 090-7 Quality Control Procedures - General Immunology

- Changed the language: ~~Moderate complexity~~ Kits with procedural (internal) controls;

Syphilis Serology (090)(9)(e)

- Changed the requirement for testing positive and negative reference materials with each test run to each day of testing;

Tables 090-8 & 9 Quality Control Procedures - Bacteriology & AST

- Changed the QC requirements from each day or week of use to each batch, shipment and new lot number for catalase, coagulase, oxidase, beta-lactamase Cefinase reagents, bacitracin, optochin, ONPG, X and V disks or strips;
- Changed acid-fast stain QC from each week of use to each day of use;
- Changed antisera QC from each month of use to every six months;
- Updated NCCLS references;

Table 090-10 Quality Control Procedures - Mycobacteriology

- Revised language to read that QC for all reagents or test procedures used for mycobacteria identification must be done using an acid-fast organism that produces a positive and negative reaction each day of use, unless otherwise specified;
- Changed acid-fast stain QC requirements to a positive and negative each day of use;
- Changed fluorochrome acid-fast stain QC to each time of use;
- Clarified that each batch of media, and each shipment lot of antimycobacterial agents used for susceptibility testing must have QC performed before or concurrent with initial use;

Table 090-11 Quality Control Procedures - Mycology

- Added: QC for lactophenol cotton blue stain must be done each batch or shipment and each lot number;
- Changed the QC requirement for acid-fast stains from each week to each day of use;
- Changed QC for reagents for biochemical and other identification test procedures from each week of use to each batch or shipment and lot number;

Cytology (090)(9)(h)

- (ii)(D) Clarified that when counting slides for the 100 slides/day limit, that slide preparation techniques (automated, semi-automated or liquid based) which results in cell dispersion over one-half or less of the total available slide may be counted as one-half slide for nongynecologic slides, NOT for gynecologic slides;
- (iii)(D) Added language that records of initial examination and rescreening results are available and documented;
- (iii)(G) Changed the requirement for correlation with histopathology reports of all abnormal cytology reports to all HSIL, adenocarcinoma, or other malignant neoplasms;

Immunohematology/Transfusion Services (090)(9)(i)

- Updated FDA citations;

Histocompatibility (090)(9)(j)

- Updated CLIA cross-reference;

Cytogenetics (090)(9)(k)

Revised language:

- (i) Document:
  - (D) Reactions observed;
  - (F) Sufficient resolution appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided ~~to support the reported results~~;
- (iv) Perform ~~confirmatory testing on all atypical results when performing~~ full chromosome analysis for determination of sex ~~by X and Y Chromatin counts~~;